BIONOSTICS AUG 2 8 2001 K012431

510(k) Summary[*]

(a) (1) **Submitter's name, address**
Bionostics, Inc.
2 Craig Road
Acton, MA 10720

Contact Person
Kathleen Storro
Director, QA & Regulatory Affairs
(978) 263-3856 x 220

Date of preparation of this summary: 27 July 2001

(2) **Device trade or proprietary name:** **COMBITROL TS and AUTOTROL TS Multi Analyte Controls**

Device common or usual name or classification name:

Multi Analyte Control Solution, All Types (Assayed and Unassayed)

	CLASSIFICATION			
PRODUCT NOMENCLATURE	NUMBER		CLASS	PANEL
MULTI ANALYTE CONTROL SOLUTION	862.1660	75 JJY	I	CHEMISTRY

(3) **Substantial Equivalence**
COMBITROL TS and AUTOTROL TS Multi Analyte Controls are substantially equivalent in function, safety and efficacy to a number of currently marketed devices known as 'Combi' or 'Multi-Analyte' control solutions. In example:

Comparison of COMBITROL TS / AUTOTROL TS to predicate devices for substantial equivalency

Characteristic	Predicate Devices		Modified Device
Name:	COMBITROL PLUS Multi-Analyte Control	AVL OPTI-check PLUS Multi-Analyte Control	COMBITROL TS AUTOTROL TS Multi Analyte Controls
510(k), Date:	K972868, 08/28/97 K913133, 09/27/91	K001632, 06/19/00	
Number of levels:	3	3	3
Analytes:	pH, PCO_2, PO_2, Na^+, K^+, Cl^-, iCa^{++} Li^+, iMg^{++}, tHb, Hb derivatives, Urea, Glucose, Lactate, Creatinine	pH, PCO_2, PO_2, Na^+, K^+, Cl^-, iCa^{++}, Urea, Glucose tHb, SO_2	pH, PCO_2, PO_2, Na^+, K^+, Cl^-, iCa^{++}, Li^+, iMg^{++}, tHb, Hct, SO_2, Urea, Glucose, Lactate, Creatinine,
Container:	glass ampoule	glass ampoule	glass ampoule
Fill volume:	1.7 mL	1.7 mL	1.7 mL
Color:	red	milky	milky
Matrix:	HEPES based aqueous with dyes to simulate Hb and derivatives	HEPES based aqueous with polystyrene beads to simulate Hb and SO_2	HEPES based aqueous with polystyrene beads to simulate Hb and SO_2

[*] This summary of safety and effectiveness is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

(4) **Description of the new device**
COMBITROL TS / AUTOTROL TS is a specially formulated aqueous liquid material intended to for use to monitor all analytes measured by the Roche OMNI, alpha series analyzers. It contains a stable suspension of polystyrene microbeads which reflect and partially absorb red and infrared light similar to erythrocytes, allowing true simulation of the measurement of tHb and SO_2 in exactly the same manner as these analytes are determined in whole blood by the Roche OMNI, alpha series analyzers. The three control levels contain three different concentrations of microbeads to simulate low, medium, and high hematocrit blood samples. COMBITROL TS / AUTOTROL TS provide a convenient method of performing periodic QC checks for laboratories selecting to measure liquid QC material as a part of their quality assurance program.

COMBITROL TS / AUTOTROL TS contain clinically relevant quantities of pH, PCO_2, PO_2, sodium, potassium, ionized calcium, chloride, lithium, ionized magnesium glucose, lactate, urea, creatinine and suitable concentrations of microbeads to simulate clinically relevant values of tHb, hematocrit and oxygen saturation.

(5) **Intended use of the device**
COMBITROL TS / AUTOTROL TS assayed controls are intended to be used to monitor and evaluate the analytical performance of the Roche OMNI, alpha series instruments for the analytes listed in the package insert..

(6) **Technological characteristics of the device.**
COMBITROL TS / AUTOTROL TS assayed control is intended to be used to monitor and evaluate the analytical performance of the Roche OMNI, alpha series instruments for the analytes listed in the package insert is technologically equivalent to currently marketed products to which substantial equivalence is claimed. It contains a low concentration, stable suspension of polystyrene microbeads which reflect and partially absorb red and infrared light similar to erythrocytes, allowing true simulation of the measurement of tHb, hematocrit and SO_2 in exactly the same manner as these analytes are determined in whole blood by the Roche OMNI, alpha series instruments.

(b) (1) **Summary of non-clinical tests submitted with the premarket notification for the device.**
Accelerated aging studies on most labile analytes, together with experience with other products with similar formulations support stability claim.

(b) (2) **Summary of clinical tests submitted with the premarket notification for the device.**
N/A

(b) (3) **Conclusions drawn from the clinical and non-clinical trials.**
Comparison of technological characteristics, formulation and intended use to predicate devices listed in this summary support the claim of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 2 8 2001

Ms. Kathleen Storro
Director, QA and Regulatory Affairs
Bionostics, Inc.
2 Craig Road
Acton, MA 01720

Re: K012431
Trade/Device Name: COMBITROL TS / AUTOTROL TS Multi-Analyte Controls
Regulation Number: 21 CFR 862.1660
Regulatory Class: I, reserved
Product Code: JJS, JJY
Dated: July 27, 2001
Received: July 31, 2001

Dear Ms. Storro:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K012431

Device Name: **COMBITROL TS / AUTOTROL TS**
Multi-Analyte Controls

COMBITROL TS / AUTOTROL TS assayed controls are intended to be used to monitor and evaluate the analytical performance of the Roche OMNI, alpha series instruments for the analytes listed in the package insert.

For *In Vitro* Diagnostic Use

Indications for Use:

As a part of the quality control program in institutions reporting those analytes listed in the package insert, COMBITROL TS and AUTOTROL TS Multi-Analyte Controls should be used in Roche OMNI, alpha series instruments to evaluate test precision and to detect systematic analytical deviations in those laboratories choosing to use a traditional, liquid, quality control product.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Kesia Alexander for Jean Cooper (Optional Format 1-2-96)
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012431